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April 9, 2002

#24

**VIA HAND DELIVERY**

**Hand-Delivery Address:**

Ms. Karin Tyson  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner for  
Patent Examination Policy  
United States Patent and Trademark Office  
Crystal Plaza 3-D09  
2021 South Clark Place  
Arlington, VA 22202

Re: Application for Extension of Patent Term, Reissue Patent No. 36,755, Issued:  
January 27, 1998; "*DNA Encoding Tumor Necrosis Factor – Alpha and Beta  
Receptors*", Smith et. al.  
Assignee: Immunex Corporation  
Atty. Dkt.: IMM200/58000/4-001EX

Dear Ms. Tyson:

With regard to the above-referenced Patent Term Extension Application, enclosed please find the following for inclusion in your files:

- 1) Additional copy of Power of Attorney and General Authority from Agent of Assignee dated 8/25/00;
- 2) Transmittal letter and Supplemental Application for Extension of Patent Term Based on Regulatory Review of a New Drug Application dated 8/31/00, including Exhibits;
- 3) Request for Additional Certified Copies of Patent Term Extension Certificate; and
- 4) Return postcard.

Please date-stamp and return the enclosed postcard to evidence receipt of these documents.

Ms. Karin Tyson

Page 2

April 9, 2002

Per our telephone conversation today, and in accordance with Attachment 1 (additional copy of Power of Attorney), please direct all future correspondence to the following:

Tracey B. Davies  
Vinson & Elkins L.L.P.  
2300 First City Tower  
1001 Fannin Street  
Houston, Texas 77002-6760  
(512) 495-8619  
(512) 236-3215 (Fax)

Thank you very much for your time and assistance with this matter. If you have any questions, please do not hesitate to contact me.

Very truly yours,

A handwritten signature in black ink, appearing to read "Tracey B. Davies", written in a cursive style.

Tracey B. Davies

1498:3058

Enclosures

cc: Michael Kirschner (w/o encls.)  
Gordon Kit (w/o encls.)  
Marya Breig, Docket Specialist (w/o encls.)

271273\_1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: US Patent No. RE 36,755  
Issued: June 27, 2000  
Inventors: Smith, Craig A., Seattle, Washington  
Goodwin, Raymond G., Seattle, Washington  
Beckmann, M. Patricia, Poulsbo, Washington  
Assignee: Immunex Corporation, Seattle, Washington  
For: DNA Encoding Tumor Necrosis Factor- alpha and - beta receptors

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REEXAM UNIT

**POWER OF ATTORNEY AND GENERAL  
AUTHORITY FROM AGENT OF ASSIGNEE**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Immunex Corporation hereby certifies that it is the assignee of the entire right, title and interest in the patent, and reissue application for patent.

The undersigned (whose title is supplied below) is empowered to act on behalf of the agent of said assignee.

The undersigned has reviewed all of the documents in the chain of title of the patent identified above and, to the best of undersigned's knowledge and belief, title is in the assignee identified above.

The agent of said assignee hereby appoints Willem G. Schuurman (Reg. No. 29,998); Gregory L. Porter (Reg. No. 40,131); Andrew G. DiNovo (Reg. No. 40,115); Minh-Hien Nguyen (Reg. No. 37,294); Adam V. Floyd (Reg. No. 39,192); Timothy S. Corder (Reg. No. 38,414); Brian K. Buss (Reg. No. 42,375); Tracey B. Davies (Reg. No. 44,644); Stephen J. Moloney (Reg. No. 44,947); David B. Weaver (Reg. No. 43,244) as its attorneys or agents with full power of substitution and revocation to transact all business in the Patent and Trademark Office in connection with the above-identified patent, including, but not limited to, filing for patent term extensions under 35 U.S.C. § 156. The agent of said assignee requests that all correspondence and telephone communications be directed to the following person at the mailing address and telephone number hereafter given:

Tracey B. Davies  
VINSON & ELKINS L.L.P.  
2300 First City Tower  
1001 Fannin Street  
Houston, Texas 77002-6760  
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The undersigned hereby declares that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the patent.

ASSIGNEE:

IMMUNEX CORPORATION

By: Michael Kirschner

Name: Michael Kirschner

Title: Vice President, <sup>MR</sup> of Intellectual Property

Date: August 25, 2000

# Vinson & Elkins

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August 31, 2000

**Box: Patent Ext.**  
Commissioner for Patents  
Washington, D.C. 20231

*RE: Application for Extension of Patent Term, Patent No.: 5,712,155, Issued:  
January 27, 1998; "DNA Encoding Tumor Necrosis Factor - Alpha and  
- Beta Receptors", Smith et al.  
Assignee: Immunex Corporation  
Atty. Dkt: IMM200/58000/4-001EX*

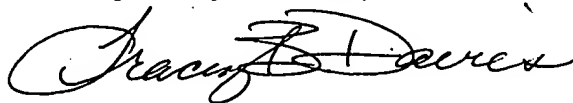
Sir:

The following documents are being forwarded herewith for appropriate action by the U.S. Patent and Trademark Office:

1. Supplement to Application for Extension of Patent Term Based on Regulatory Review of a New Drug Application as Provided Under 35 U.S.C. § 156(D)(1) (in duplicate);
2. Exhibits 1-3 (in duplicate);
3. A return postcard to evidence receipt of these materials. Please date stamp and return this postcard.

It is believed that no fees are due in connection with this filing. Should it be determined that fees are required, the Commissioner is hereby authorized to deduct such fees from Vinson & Elkins L.L.P. deposit account no. 22-0365/IMM200/4-001EX.

Respectfully submitted,



Tracey B. Davies  
Attorney for Applicant  
Reg. No. 44,644

1498:9311  
Enclosures

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re: U.S. Patent Re 36,755 (Reissue of U.S. Patent No. 5,712,155)

Issued: June 27, 2000 (Issue date of original patent: January 27, 1998)

Inventor: Smith, Craig A., Seattle, Washington  
Goodwin, Raymond G., Seattle, Washington  
Beckmann, M. Patricia, Poulsbo, Washington

Assignee: Immunex Corporation, Seattle, Washington

For: DNA encoding tumor necrosis factor -alpha and -beta receptors

Commissioner for Patents  
Box Patent Extension  
Washington, D.C. 20231

**SUPPLEMENT TO APPLICATION FOR  
EXTENSION OF PATENT TERM BASED ON  
REGULATORY REVIEW OF A NEW DRUG APPLICATION  
AS PROVIDED UNDER 35 U.S.C. § 156(D)(1)**

Sir:

On December 22, 1998 an application for extension of patent term based on regulatory review of a new drug application, as provided under 35 U.S.C. § 156(D)(1) was filed in this matter. This application made all arguments and references to the pending re-issue patent, filed from issued U.S. Patent 5,712,155. On June 27, 2000, that reissue patent (Re. 36,755) was issued by the patent office.

This paper is filed to update the original patent term extension application. The information previously provided is supplemented as follows:

- I. **37 C.F.R. §1.740(a)(6): A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration.**

<b>Response in Original Request for Patent Term Extension</b>	<b>Updated Information</b>
This application for extension relates to the reissue patent expected to be granted with respect to U.S. patent 5,712,155, issued on	This application for extension relates to Re. 36,755, issued June 27, 2000, from U.S. patent 5,712,155.

January 27, 1998, on an application filed November 29, 1994, as a continuation of U.S. Ser. No. 523,635, filed May 10, 1990, now U.S. patent 5,395,760, which is a continuation-in-part of U.S. Ser. No. 421,417, filed October 13, 1989, now abandoned which is a continuation-in-part of U.S. Ser. No. 405,370, filed September 11, 1989 now abandoned, which is a continuation-in-part of U.S. Ser. No. 403,241, filed September 5, 1989, now abandoned. The term of this patent subsequent to March 7, 2012 has been disclaimed.	The remainder of the information remains the same.
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**II. 37 C.F.R. §1.740(a)(7) A copy of the patent for which an extension is being sought, including the entire specification (including claims) and drawings.**

Response in Original Request for Patent Term Extension	Updated Information
A copy of the application for the reissue patent for which an extension is being sought, including the entire specification (including claims) appears in Exhibit B, together with U.S. patent 5,172,155.	A copy of Re. 36,755, including the entire specification and claims, is attached hereto as Exhibit 1.

**III. 37 C.F.R. §1.740(a)(8): A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent.**

Response in Original Request for Patent Term Extension	Updated Information
The reissue patent for which extension is being sought has been the subject of disclaimer of the term subsequent to March 7, 2012. A copy of the disclaimer is provided as Exhibit C. <i>The U.S. patent on which the reissue is based has not been the subject of a certificate of correction.</i> A copy of the reissue application and the amendments made via reissue is attached as Exhibit B. The U.S. patent on which the reissue is base has not been subject to a reexamination. No maintenance fees have become due or payable as of the date of this application for extension.	The U.S. Patent (5,712,155) upon which Re 36,755 is based was the subject of a Certificate of Correction, a copy of which is attached hereto as Exhibit 2. It consists of corrections to claim 10 of U.S. Patent No. 5,712,155. The corrections are reflected in Re. 36,755.

**IV. 37 C.F.R. §1.740(a)(9): Comparison of pending reissue claims, upon which the original application for extension of patent term was based, and the issued claims of reissue patent 36,755**

The relationship between the claims of then-pending reissue patent 36,755 and the approved product was clearly set forth in the Application for Patent Term Extension filed December 22, 1998, in accordance with the requirements of 37 C.F.R. § 1.740(a)(9). **There are no changes to this information. Applicant's re-affirm that the approved product, the active ingredient in Enbrel™ lyophilized powder, remains claimed by the patent that is the subject of this patent term extension application (RE 36,755).** Minor differences in the issued claims of Re 36,755 as compared to the pending claims on December 22, 1998 are set forth below for the sake of clarity.

<b>Claims Pending at Time of Original Request for Patent Term Extension</b>	<b>Claims as Issued in Re 36,755 (changes indicated by conventional amendment form)</b>
18. An isolated DNA molecule encoding a protein <i>comprising a sequence of amino acids selected from the group consisting of amino acids 1-163 of FIG. 2A and amino acids 1-233 of FIG. 3A</i> , wherein said protein is capable of binding TNF.	18. An isolated DNA molecule encoding a protein comprising a sequence of amino acids selected from the group consisting of amino acids 1-163 of [FIG. 2A] <u>SEQ ID NO:1</u> and amino acids 1-233 of [FIG. 3A] <u>SEQ ID NO:3</u> , wherein said protein is capable of binding TNF.
19. The isolated DNA molecule according to Claim 18, <i>wherein said protein comprises amino acids 1-163 of FIG. 2A.</i>	19. The isolated DNA molecule according to Claim 18, wherein said protein comprises amino acids 1-163 of [FIG. 2A] <u>SEQ ID NO:1</u> .
20. The isolated DNA molecule according to Claim 18, wherein <i>said protein comprises amino acids 1-185 of FIG. 2A.</i>	20. The isolated DNA molecule according to Claim 18, wherein said protein comprises amino acids 1-185 of [FIG. 2A] <u>SEQ ID NO:1</u> .
21. The isolated DNA molecule according to Claim 18, wherein said protein <i>comprises amino acids 1-235 of FIG. 2A.</i>	21. The isolated DNA molecule according to Claim 18, wherein said protein comprises amino acids 1-235 of [FIG. 2A] <u>SEQ ID NO:1</u> .
22. An isolated DNA molecule encoding a protein selected from the group consisting of: (a) <i>a polypeptide having a sequence of amino acids comprising amino acids 1-163 of FIG. 2A;</i> (b) <i>a polypeptide having a sequence of amino acids comprising amino acids 1-233 of FIG. 3A; and</i> (c) <i>a polypeptide identical to the polypeptides of (a) or (b) except for one or more modification(s) to the sequence of amino acids selected from the group consisting of: (i) inactivated N-linked glycosylation sites; (ii) altered KEX2</i>	22. An isolated DNA molecule encoding a protein selected from the group consisting of: (a) a polypeptide having a sequence of amino acids comprising amino acids 1-163 of [FIG. 2A] <u>SEQ ID NO:1</u> ; (b) a polypeptide having a sequence of amino acids comprising amino acids 1-233 of [FIG. 3A] <u>SEQ ID NO:3</u> ; and (c) a polypeptide identical to the polypeptides of (a) or (b) except for one or more modification(s) to the sequence of amino acids selected from the group consisting of: (i) inactivated N-linked glycosylation sites; (ii)



protease cleavage sites; and (iii) substitution or deletion of cysteine residues, wherein said protein is capable of binding TNF.	altered KEX2 protease cleavage sites; and (iii) substitution or deletion of cysteine residues, wherein said protein is capable of binding TNF.
23. A recombinant expression vector comprising the DNA molecule according to Claim 18, 19, 20, 21 or 22.	23. A recombinant expression vector comprising the DNA molecule according to Claim 18, 19, 20, 21 or 22.
24. A host cell transformed or transfected with the recombinant expression vector according to Claim 23.	24. A host cell transformed or transfected with the recombinant expression vector according to Claim 23.
25. The host cell of Claim 24, wherein said host cell is selected from the group consisting of a microbial cell and a mammalian cell.	25. The host cell of Claim 24, wherein said host cell is selected from the group consisting of [a] microbial [cell] <u>cells</u> and [a] mammalian [cell] <u>cells</u> .
26. The host cell of Claim 25, wherein said mammalian cell is selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.	26. The host cell of Claim 25, wherein said mammalian [cell is] <u>cells are</u> selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.
27. The host cell of Claim 26, wherein said mammalian cell is CHO cells.	27. The host cell of Claim 26, wherein said mammalian [cell is] <u>cells are</u> CHO cells.
28. A process for producing a protein capable of binding TNF, said process comprising culturing a host cell of Claim 24 under conditions suitable to effect expression of said protein	28. A process for producing a protein capable of binding TNF, said process comprising culturing a host cell of Claim 24 under conditions suitable to effect expression of said protein
29. The process of Claim 28, wherein said host cell is selected from the group consisting of a microbial cell and a mammalian cell.	29. The process of Claim 28, wherein said host cell is selected from the group consisting of [a] microbial [cell] <u>cells</u> and [a] mammalian [cell] <u>cells</u> .
30. The process of Claim 29, wherein said mammalian cell is selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.	30. The process of Claim 29, wherein said mammalian [cell is] <u>cells are</u> selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.
31. The process of Claim 30, wherein said mammalian cell is CHO cells.	31. The process of Claim 30, wherein said mammalian [cell is] <u>cells are</u> CHO cells.
32. An isolated DNA molecule encoding a soluble TNF receptor protein comprising a sequence of <i>amino acids selected from the group consisting of from about amino acid 1 to about amino acid 163 of FIG. 2A</i> and from about amino acid 1 to about amino acid 233 of FIG. 3A, wherein said soluble TNF receptor protein is capable of binding TNF protein.	32. An isolated DNA molecule encoding a soluble TNF receptor protein comprising a sequence of amino acids selected from the group consisting of from about amino acid 1 to about amino acid 163 of [FIG. 2A] <u>SEQ ID NO:1</u> and from about amino acid 1 to about amino acid 233 of [FIG. 3A] <u>SEQ ID NO:3</u> , wherein said soluble TNF receptor protein is capable of binding TNF protein.
33. The isolated DNA molecule according to Claim 32, wherein said soluble TNF	33. The isolated DNA molecule according to Claim 32, wherein said soluble TNF

receptor protein comprises <i>from about amino acid 1 to about amino acid 163 of FIG. 2A.</i>	receptor protein comprises from about amino acid 1 to about amino acid 163 of [FIG. 2A] <u>SEQ ID NO:1.</u>
34. The isolated DNA molecule according to Claim 32, wherein said soluble TNF receptor protein comprises from <i>about amino acid 1 to about amino acid 185 of FIG. 2A.</i>	34. The isolated DNA molecule according to Claim 32, wherein said soluble TNF receptor protein comprises from about amino acid 1 to about amino acid 185 of [FIG. 2A] <u>SEQ ID NO:1.</u>
35. The isolated DNA molecule according to Claim 32, wherein said TNF soluble receptor protein comprises <i>from about amino acid 1 to about amino acid 235 of FIG. 2A.</i>	35. The isolated DNA molecule according to Claim 32, wherein said TNF soluble receptor protein comprises from about amino acid 1 to about amino acid 235 of [FIG. 2A] <u>SEQ ID NO:1.</u>
36. An isolated DNA molecule encoding a soluble TNF receptor protein selected from the group consisting of: (a) a TNF receptor polypeptide having a sequence of amino acids comprising <i>from about amino acid 1 to about amino acid 163 of FIG. 2A</i> ; (b) a TNF receptor polypeptide having a sequence of amino acids comprising from about amino acid 1 to about amino acid 233 of FIG. 3A; and (c) a TNF receptor polypeptide identical to the TNF receptor polypeptides of (a) or (b) except for one or more modification(s) to the sequence of amino acids selected from the group consisting of: (i) inactivated N-linked glycosylation sites; (ii) altered KEX2 protease cleavage sites; and (iii) substitution or deletion of cysteine residues, wherein said soluble TNF receptor protein is capable of binding TNF.	36. An isolated DNA molecule encoding a soluble TNF receptor protein selected from the group consisting of: (a) a TNF receptor polypeptide having a sequence of amino acids comprising from about amino acid 1 to about amino acid 163 of [FIG. 2A] <u>SEQ ID NO:1</u> ; (b) a TNF receptor polypeptide having a sequence of amino acids comprising from about amino acid 1 to about amino acid 233 of [FIG. 3A] <u>SEQ ID NO:3</u> ; and (c) a TNF receptor polypeptide identical to the TNF receptor polypeptides of (a) or (b) except for one or more modification(s) to the sequence of amino acids selected from the group consisting of: (i) inactivated N-linked glycosylation sites; (ii) altered KEX2 protease cleavage sites; and (iii) substitution or deletion of cysteine residues, wherein said soluble TNF receptor protein is capable of binding TNF.
37. A recombinant expression vector comprising the DNA molecule according to Claim 32, 33, 34, 35 or 36.	37. A recombinant expression vector comprising the DNA molecule according to Claim 32, 33, 34, 35 or 36.
38. A host cell transformed or transfected with the recombinant expression vector according to Claim 37.	38. A host cell transformed or transfected with the recombinant expression vector according to Claim 37.
39. The host cell of Claim 38, wherein said host cell is selected from the group consisting	39. The host cell of Claim 38, wherein said host cell is selected from the group consisting

of a microbial cell and a mammalian cell.	of [a] microbial [cell] <u>cells</u> and [a] mammalian [cell] <u>cells</u> .
40. The host cell of Claim 39, wherein said mammalian cell is selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.	40. The host cell of Claim 39, wherein said mammalian [cell is] <u>cells are</u> selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.
41. The host cell of Claim 40, wherein said mammalian cell is CHO cells.	41. The host cell of Claim 40, wherein said mammalian [cell is] <u>cells are</u> CHO cells.
42. A process for producing a protein capable of binding TNF, said process comprising culturing a host cell of Claim 38 under conditions suitable to effect expression of said protein.	42. A process for producing a protein capable of binding TNF, said process comprising culturing a host cell of Claim 38 under conditions suitable to effect expression of said protein.
43. The process of Claim 42, wherein said host cell is selected from the group consisting of a microbial cell and a mammalian cell.	43. The process of Claim 42, wherein said host cell is selected from the group consisting of [a] microbial [cell] <u>cells</u> and [a] mammalian [cell] <u>cells</u> .
44. The process of Claim 43, wherein said mammalian cell is selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.	44. The process of Claim 43, wherein said mammalian [cell is] <u>cells are</u> selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.
45. The process of Claim 44, wherein said mammalian cell is CHO cells.	45. The process of Claim 44, wherein said mammalian [cell is] <u>cells are</u> CHO cells.
46. An isolated DNA molecule encoding a soluble TNF receptor protein comprising a sequence of <i>amino acids selected from the group consisting of from amino acid 1 to amino acid 163 of FIG. 2A</i> and from amino acid 1 to amino acid 233 of FIG. 3A, wherein said soluble TNF receptor protein is capable of binding TNF protein.	46. An isolated DNA molecule encoding a soluble TNF receptor protein comprising a sequence of amino acids selected from the group consisting of from amino acid 1 to amino acid 163 of [FIG. 2A] <u>SEQ ID NO:1</u> and from amino acid 1 to amino acid 233 of [FIG. 3A] <u>SEQ ID NO:3</u> , wherein said soluble TNF receptor protein is capable of binding TNF protein.
47. The isolated DNA molecule according to Claim 46, wherein said soluble TNF receptor protein <i>comprises from amino acid 1 to amino acid 163 of FIG. 2A</i> .	47. The isolated DNA molecule according to Claim 46, wherein said soluble TNF receptor protein comprises from amino acid 1 to amino acid 163 of [FIG. 2A] <u>SEQ ID NO:1</u> .
48. The isolated DNA molecule according to Claim 46, wherein said soluble TNF receptor protein <i>comprises from amino acid 1 to amino acid 185 of FIG. 2A</i> .	48. The isolated DNA molecule according to Claim 46, wherein said soluble TNF receptor protein comprises from amino acid 1 to amino acid 185 of [FIG. 2A] <u>SEQ ID NO:1</u> .
49. The isolated DNA molecule according to Claim 46, wherein said soluble TNF receptor protein <i>comprises from amino acid 1 to amino acid 235 of FIG. 2A</i> .	49. The isolated DNA molecule according to Claim 46, wherein said soluble TNF receptor protein comprises from amino acid 1 to amino acid 235 of [FIG. 2A] <u>SEQ ID NO:1</u> .
50. An isolated DNA molecule encoding a soluble TNF receptor protein selected from the	50. An isolated DNA molecule encoding a soluble TNF receptor protein selected from the

<p>group consisting of:</p> <p>(a) a TNF receptor polypeptide having a sequence of amino acids <b><i>comprising from amino acid 1 to amino acid 163 of FIG. 2A;</i></b></p> <p>(b) a TNF receptor polypeptide having a sequence of amino acids comprising from amino acid 1 to amino acid 233 of FIG. 3A; and</p> <p>(c) a TNF receptor polypeptide identical to the TNF receptor polypeptides of (a) or (b) except for one or more modification(s) to the sequence of amino acids selected from the group consisting of: (i) inactivated N-linked glycosylation sites; (ii) altered KEX2 protease cleavage sites; and (iii) substitution or deletion of cysteine residues,</p> <p>wherein said soluble TNF receptor protein is capable of binding TNF.</p> <p><i>Note: A typographical error in the first submission resulted in claim 33 being reproduced here.</i></p>	<p>group consisting of:</p> <p>(a) a TNF receptor polypeptide having a sequence of amino acids comprising from amino acid 1 to amino acid 163 of [FIG. 2A] <u>SEQ ID NO:1</u>;</p> <p>(b) a TNF receptor polypeptide having a sequence of amino acids comprising from amino acid 1 to amino acid 233 of [FIG. 3A] <u>SEQ ID NO:3</u>; and</p> <p>(c) a TNF receptor polypeptide identical to the TNF receptor polypeptides of (a) or (b) except for one or more modification(s) to the sequence of amino acids selected from the group consisting of: (i) inactivated N-linked glycosylation sites; (ii) altered KEX2 protease cleavage sites; and (iii) substitution or deletion of cysteine residues,</p> <p>wherein said soluble TNF receptor protein is capable of binding TNF.</p>
51. A recombinant expression vector comprising the DNA molecule according to Claim 46, 47, 48, 49 or 50.	51. A recombinant expression vector comprising the DNA molecule according to Claim 46, 47, 48, 49 or 50.
52. A host cell transformed or transfected with the recombinant expression vector according to Claim 51.	52. A host cell transformed or transfected with the recombinant expression vector according to Claim 51.
53. The host cell of Claim 52, wherein said host cell is selected from the group consisting of a microbial cell and a mammalian cell.	53. The host cell of Claim 52, wherein said host cell is selected from the group consisting of [a] microbial [cell] <u>cells</u> and [a] mammalian [cell] <u>cells</u> .
54. The host cell of Claim 53, wherein said mammalian cell is selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.	54. The host cell of Claim 53, wherein said mammalian [cell is] <u>cells are</u> selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.
55. The host cell of Claim 54, wherein said mammalian cell is CHO cells.	55. The host cell of Claim 54, wherein said mammalian [cell is] <u>cells are</u> CHO cells.
56. A process for producing a protein capable of binding TNF, said process comprising culturing a host cell of Claim 52 under conditions suitable to gffect expression of said protein.	56. A process for producing a protein capable of binding TNF, said process comprising culturing a host cell of Claim 52 under conditions suitable to effect expression of said protein.
57. The process of Claim 56, wherein said	57. The process of Claim 56, wherein said

host cell is selected from the group consisting of a microbial cell and a mammalian cell.	host cell is selected from the group consisting of [a] microbial [cell] <u>cells</u> and [a] mammalian [cell] <u>cells</u> .
58. The process of Claim 57, wherein said mammalian cell is selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.	58. The process of Claim 57, wherein said mammalian [cell is] <u>cells are</u> selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.
59. The process of Claim 58, wherein said mammalian cell is CHO cells.	59. The process of Claim 58, wherein said mammalian [cell is] <u>cells are</u> CHO cells.
60. An isolated DNA molecule encoding a protein comprising a sequence of amino acids selected from the group <i>consisting of amino acids 1-163 of FIG. 2A</i> and amino acids 1-233 of FIG. 3A, <i>wherein said protein lacks amino acids 236-265 of FIG. 2A</i> and amino acids 234-265 of FIG. 3A, respectively, and wherein said protein is capable of binding TNF.	60. An isolated DNA molecule encoding a protein comprising a sequence of amino acids selected from the group consisting of amino acids 1-163 of [FIG. 2A] <u>SEQ ID NO:1</u> and amino acids 1-233 of [FIG. 3A] <u>SEQ ID NO:3</u> , wherein said protein lacks amino acids 236-265 of [FIG. 2A] <u>SEQ ID NO:1</u> and amino acids 234-265 of [FIG. 3A] <u>SEQ ID NO:3</u> , respectively, and wherein said protein is capable of binding TNF.
61. The isolated DNA molecule according to Claim 60, wherein said protein <i>comprises amino acids 1-163 of FIG. 2A</i> .	61. The isolated DNA molecule according to Claim 60, wherein said protein comprises amino acids 1-163 of [FIG. 2A] <u>SEQ ID NO:1</u> .
62. The isolated DNA molecule according to Claim 60, wherein said protein <i>comprises amino acids 1-185 of FIG. 2A</i> .	62. The isolated DNA molecule according to Claim 60, wherein said protein comprises amino acids 1-185 of [FIG. 2A] <u>SEQ ID NO:1</u> .
63. The isolated DNA molecule according to Claim 60, wherein said protein <i>comprises amino acids 1-235 of FIG. 2A</i> .	63. The isolated DNA molecule according to Claim 60, wherein said protein comprises amino acids 1-235 of [FIG. 2A] <u>SEQ ID NO:1</u> .
64. An isolated DNA molecule encoding a protein selected from the group consisting of: (a) a TNF receptor polypeptide having a sequence of amino acids <i>comprising amino acids 1-163 of FIG. 2A</i> , wherein said polypeptide <i>lacks amino acids 236-265 of FIG. 2A</i> ; (b) a TNF receptor polypeptide having a sequence of amino acids comprising amino acids 1-233 of FIG. 3A, wherein said polypeptide lacks amino acids 234-265 of FIG. 3A; and (c) a TNF receptor polypeptide identical to the TNF receptor polypeptides of (a) or (b) except for one or more modification(s) to the sequence of amino acids selected from the group consisting of: (i)	64. An isolated DNA molecule encoding a protein selected from the group consisting of: (a) a TNF receptor polypeptide having a sequence of amino acids comprising amino acids 1-163 of [FIG. 2A] <u>SEQ ID NO:1</u> , wherein said polypeptide lacks amino acids 236-265 of [FIG. 2A] <u>SEQ ID NO:1</u> ; (b) a TNF receptor polypeptide having a sequence of amino acids comprising amino acids 1-233 of [FIG. 3A] <u>SEQ ID NO:3</u> , wherein said polypeptide lacks amino acids 234-265 of [FIG. 3A] <u>SEQ ID NO:3</u> ; and (c) a TNF receptor polypeptide identical to the TNF receptor polypeptides of (a) or (b) except for one or more modification(s) to the sequence of amino acids selected from the group consisting of: (i)

inactivated N-linked glycosylation sites; (ii) altered KEX2 protease cleavage sites; and (iii) substitution or deletion of cysteine residues, wherein said protein is capable of binding TNF.	inactivated N-linked glycosylation sites; (ii) altered KEX2 protease cleavage sites; and (iii) substitution or deletion of cysteine residues, wherein said protein is capable of binding TNF.
65. A recombinant expression vector comprising the DNA molecule according to Claim 60, 61, 62, 63 or 64.	65. A recombinant expression vector comprising the DNA molecule according to Claim 60, 61, 62, 63 or 64.
66. A host cell transformed or transfected with the recombinant expression vector according to Claim 65.	66. A host cell transformed or transfected with the recombinant expression vector according to Claim 65.
67. The host cell of Claim 66, wherein said host cell is selected from the group consisting of a microbial cell and a mammalian cell.	67. The host cell of Claim 66, wherein said host cell is selected from the group consisting of [a] microbial [cell] <u>cells</u> and [a] mammalian [cell] <u>cells</u> .
68. The host cell of Claim 67, wherein said mammalian cell is selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.	68. The host cell of Claim 67, wherein said mammalian cell is selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.
69. The host cell of Claim 68, wherein said mammalian cell is CHO cells.	69. The host cell of Claim 68, wherein said mammalian [cell is] <u>cells are</u> CHO cells.
70. A process for producing a protein capable of binding TNF, said process comprising culturing a host cell of Claim 67 under conditions suitable to effect expression of said protein.	70. A process for producing a protein capable of binding TNF, said process comprising culturing a host cell of Claim 67 under conditions suitable to effect expression of said protein.
71. The process of Claim 70, wherein said host cell is selected from the group consisting of a microbial cell and a mammalian cell.	71. The process of Claim 70, wherein said host cell is selected from the group consisting of [a] microbial [cell] <u>cells</u> and [a] mammalian [cell] <u>cells</u> .
72. The process of Claim 71, wherein said mammalian cell is selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.	72. The process of Claim 71, wherein said mammalian [cell is] <u>cells are</u> selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.
73. The process of Claim 72, wherein said mammalian cell is CHO cells.	73. The process of Claim 72, wherein said mammalian [cell is] <u>cells are</u> CHO cells.
74. An isolated DNA molecule encoding a protein comprising a sequence of amino acids selected from the group <i>consisting of amino acids 1-163 of FIG. 2A and amino acids 1-233 of FIG. 3A, wherein said protein lacks a functional transmembrane region</i> , and wherein said protein is capable of binding TNF.	74. An isolated DNA molecule encoding a protein comprising a sequence of amino acids selected from the group consisting of amino acids 1-163 of [FIG. 2A] <u>SEQ ID NO:1</u> and amino acids 1-233 of [FIG. 3A] <u>SEQ ID NO:3</u> , wherein said protein lacks a functional transmembrane region, and wherein said protein is capable of binding TNF.
75. The isolated DNA molecule according to Claim 74, wherein said protein <i>comprises</i>	75. The isolated DNA molecule according to Claim 74, wherein said protein comprises

<b><i>amino acids 1-163 of FIG. 2A.</i></b>	<b>amino acids 1-163 of [FIG. 2A] SEQ ID NO:1.</b>
76. The isolated DNA molecule according to Claim 74, wherein said protein <b><i>comprises amino acids 1-185 of FIG. 2A.</i></b>	76. The isolated DNA molecule according to Claim 74, wherein said protein comprises amino acids 1-185 of [FIG. 2A] <b>SEQ ID NO:1.</b>
77. The isolated DNA molecule according to Claim 74, wherein said protein <b><i>comprises amino acids 1-235 of FIG. 2A.</i></b>	77. The isolated DNA molecule according to Claim 74, wherein said protein comprises amino acids 1-235 of [FIG. 2A] <b>SEQ ID NO:1.</b>
78. An isolated DNA molecule encoding a protein selected from the group consisting of: (a) a TNF receptor polypeptide having a sequence of amino acids <b><i>comprising amino acids 1-163 of FIG. 2A;</i></b> (b) a TNF receptor polypeptide having a sequence of amino acids comprising amino acids 1-233 of FIG. 3A; and (c) a TNF receptor polypeptide identical to the TNF receptor polypeptides of (a) or (b) except for one or more modification(s) to the sequence of amino acids selected from the group consisting of: (i) inactivated N-linked glycosylation sites; (ii) altered KEX2 protease cleavage sites; and (iii) substitution or deletion of cysteine residues, wherein said protein lacks a functional transmembrane region; and wherein said protein is capable of binding TNF.	78. An isolated DNA molecule encoding a protein selected from the group consisting of: (a) a TNF receptor polypeptide having a sequence of amino acids comprising amino acids 1-163 of [FIG. 2A] <b>SEQ ID NO:1;</b> (b) a TNF receptor polypeptide having a sequence of amino acids comprising amino acids 1-233 of [FIG. 3A] <b>SEQ ID NO:3;</b> and (c) a TNF receptor polypeptide identical to the TNF receptor polypeptides of (a) or (b) except for one or more modification(s) to the sequence of amino acids selected from the group consisting of: (i) inactivated N-linked glycosylation sites; (ii) altered KEX2 protease cleavage sites; and (iii) substitution or deletion of cysteine residues, wherein said protein lacks a functional transmembrane region; and wherein said protein is capable of binding TNF.
79. A recombinant expression vector comprising the DNA molecule according to Claim 74, 75, 76, 77 or 78.	79. A recombinant expression vector comprising the DNA molecule according to Claim 74, 75, 76, 77 or 78.
80. A host cell transformed or transfected with the recombinant expression vector according to Claim 79.	80. A host cell transformed or transfected with the recombinant expression vector according to Claim 79.
81. The host cell of Claim 80, wherein said host cell is selected from the group consisting of a microbial cell and a mammalian cell.	81. The host cell of Claim 80, wherein said host cell is selected from the group consisting of [a] microbial [cell] <b>cells</b> and [a] mammalian [cell] <b>cells.</b>
82. The host cell of Claim 81, wherein said mammalian cell is selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.	82. The host cell of Claim 81, wherein said mammalian [cell is] <b>cells are</b> selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.
83. The host cell of Claim 82, wherein said mammalian cell is CHO cells.	83. The host cell of Claim 82, wherein said mammalian [cell is] <b>cells are</b> CHO cells.
84. A process for producing a protein capable of binding TNF, said process comprising culturing a host cell of Claim 80	84. A process for producing a protein capable of binding TNF, said process comprising culturing a host cell of Claim 80

under conditions suitable to effect expression of said protein.	under conditions suitable to effect expression of said protein.
85. The process of Claim 84, wherein said host cell is selected from the group consisting of a microbial cell and a mammalian cell.	85. The process of Claim 84, wherein said host cell is selected from the group consisting of [a] microbial [cell] <u>cells</u> and [a] mammalian [cell] <u>cells</u> .
86. The process of Claim 85, wherein said mammalian cell is selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.	86. The process of Claim 85, wherein said mammalian [cell is] <u>cells are</u> selected from the group consisting of L cells, C127 cells, 3T3 cells, CHO cells, BHK cells and COS-7 cells.
87. The process of Claim 86, wherein said mammalian cell is CHO cells.	87. The process of Claim 86, wherein said mammalian [cell is] <u>cells are</u> CHO cells.



V. 37 C.F.R. § 1.740(a)(10): A statement beginning on a new page, of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period, particularly, for a patent claiming a human drug, antibiotic, or human biological product, the effective date of the investigational new drug (IND) application and the IND number; the date on which a new drug application (NDA) or a Product License Application (PLA) was initially submitted and the NDA or PLA number and the date on which the NDA was approved or the Product License issued.

Response in Original Request for Patent Term Extension	Additional Information
<p>For the Biological License Application (BLA) Approval of Enbrel™ Lyophilized Powder the following are the applicable dates:</p> <p><u>Effective date for IND app.:</u> June 26, 1992</p> <p><u>Initial Submission of BLA:</u> March 9, 1998 for Chemistry Manufacturing and Controls (CMC) portion of the BLA, and June 22, 1998 for acceptance of the completed BLA.</p> <p><u>FDA Approval for BLA:</u> November 2, 1998</p>	<p><u>IND number:</u> BB IND 45-71</p> <p><u>BLA number:</u> 98-0286</p>

**VI. 37 C.F.R. § 1.740(a)(15) The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed.**

<b>Response in Original Request for Patent Term Extension</b>	<b>Updated Information</b>
Please direct all correspondence in connection with this application to:  Robert A. Armitage Registration No: 27,417 Vinson & Elkins, L.L.P., Suite 700 1455 Pennsylvania Avenue, N.W. Washington, D.C. 20004-1008 Telephone: (202)639-6692 Facsimile: (202)639-6604.	Pursuant to the Power of Attorney attached as Exhibit 3, please direct all correspondence in connection with this application to:  Tracey B. Davies Registration No: 44,644 Vinson & Elkins, L.L.P. 2300 First City Tower 1001 Fannin Houston, Texas 77002-6760 Telephone: (512)495-8619 Facsimile: (512)236-3215.

**VII. 37 C.F.R. § 1.740(a)(16): A duplicate of the application papers, certified as such.**

Applicant hereby certifies that this supplement to the application for extension filed on December 22, 1998 is being filed in duplicate.

**VIII. 37 C.F.R. § 1.740(a)(17): An oath or declaration.**

Applicant re-affirms the following:

Applicant, through its undersigned patent attorney authorized to practice before the Patent and Trademark Office and who has general authority from the owner to act on behalf of the owner in patent matters, being duly warned that willful false statements are punishable by fine or imprisonment or both under section 1001 of Title 18, United States Code and that willful false statements and the like may jeopardize the validity of this application and the patent to which it relates, states and declares that the following statements made based on his own knowledge are true and that all statements made on information and belief are believed to be true:

(1) The undersigned is registered to practice before the Patent and Trademark Office and is making this declaration as a patent attorney who has general authority to act on behalf of the applicant in patent matters.

(2) The undersigned has reviewed and understands the contents of the application being submitted pursuant to this section;

(3) The undersigned believes the patent is subject to extension pursuant to 37 C.F.R. § 1.710;

(4) The undersigned believes an extension of the length claimed is justified under 35 U.S.C. 156 and the applicable regulations; and

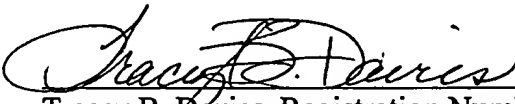
(5) The undersigned believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in 37 C.F.R. § 1.720.

It is believed that no fee is due. If a fee is warranted, the Commissioner is hereby authorized to deduct said fee from deposit account no. 22-0365/4-1. If this application for extension of patent term is held to be informal, applicant may seek to have that holding reviewed by filing a petition with the required fee, as necessary, pursuant to 37 C.F.R. §§ 1.181, 1.182 or 1.183, as appropriate, within such time as may be set in any notice that the application has been held to be informal, or if no time is set, within one month of the date on which the application was held informal.

Applicant is providing herewith in Exhibit 3 a power of attorney and general authority for the undersigned to execute this application and make the declaration required by 37 C.F.R. § 1.740(a)(17), set forth in section VIII, above.

Respectfully submitted,

Immunex Corporation

By:   
Tracey B. Davies, Registration Number 44,644  
Vinson & Elkins, L.L.P.  
600 Congress Avenue, Suite 2700  
Austin, Texas 78701  
Telephone: (512) 495-8619  
Facsimile: (512) 236-3215  
Email: tdavies@velaw.com.

Attachments:

Exhibit 1: Copy of U.S. Reissue Patent Re. 36,755.

Exhibit 2: Copy of Certificate of Correction for U.S. patent 5,712,155.

Exhibit 3: Power of Attorney and General Authority from Assignee

TBI

RECEIVED BY THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

**Proper:** Transmittal Letter  
Supplement to Application for Extension of Patent Term Based  
on Regulatory Review of a New Drug Application as Provided  
Under 35 U.S.C. § 156(D)(1) (in duplicate);  
Exhibits 1-3 (in duplicate)  
Postcard

**Inventor:** Smith *et al.*  
**Assignee:** Immunex Corporation  
**Patent No.:** 5,712,155  
**Docket No.:** IMM200/58000/4-001EX  
**Issued:** January 27, 1998  
**Entitled:** DNA ENCODING TUMOR NECROSIS FACTOR - ALPHA  
AND - BETA RECEPTORS  
**Date Sent:** August 31, 2000

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Docket Office  
Vinson & Elkins

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AUG 31 2000  
U.S. PATENT & TRADEMARK OFFICE

FROM : SUGHRUE-DC

PHONE NO. : 202+293+7860

Jul. 19 2000 03:31PM P2

UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION

PATENT NO. : 5,712,165

DATED : January 27, 1998

INVENTOR(S) : Craig A. Smith, et al

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 26, line 42, claim 10; change "adds" to - acids -.

Column 26, line 51, claim 10; change "(iv)" to - (v) -.

Column 26, line 66, claim 11; change "(ii)" to - (iii) -.

Column 27, line 16, claim 12; change "(ii)" to - (iii) -.



Attest:

*Mary H. Quinn*  
Attesting Officer

Signed and Sealed this

Eighteenth Day of August, 1998

*Bruce Lehman*

BRUCE LEHMAN

Commissioner of Patents and Trademarks

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re: US Patent No. RE 36,755  
Issued: June 27, 2000  
Inventors: Smith, Craig A., Seattle, Washington  
Goodwin, Raymond G., Seattle, Washington  
Beckmann, M. Patricia, Poulsbo, Washington  
Assignee: Immunex Corporation, Seattle, Washington  
For: DNA Encoding Tumor Necrosis Factor- alpha and - beta receptors

**POWER OF ATTORNEY AND GENERAL  
AUTHORITY FROM AGENT OF ASSIGNEE**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Immunex Corporation hereby certifies that it is the assignee of the entire right, title and interest in the patent, and reissue application for patent.

The undersigned (whose title is supplied below) is empowered to act on behalf of the agent of said assignee.

The undersigned has reviewed all of the documents in the chain of title of the patent identified above and, to the best of undersigned's knowledge and belief, title is in the assignee identified above.

The agent of said assignee hereby appoints Willem G. Schuurman (Reg. No. 29,998); Gregory L. Porter (Reg. No. 40,131); Andrew G. DiNovo (Reg. No. 40,115), Minh-Hien Nguyen (Reg. No. 37,294); Adam V. Floyd (Reg. No. 39,192); Timothy S. Corder (Reg. No. 38,414); Brian K. Buss (Reg. No. 42,375); Tracey B. Davies (Reg. No. 44,644); Stephen J. Moloney (Reg. No. 44,947); David B. Weaver (Reg. No. 43,244) as its attorneys or agents with full power of substitution and revocation to transact all business in the Patent and Trademark Office in connection with the above-identified patent, including, but not limited to, filing for patent term extensions under 35 U.S.C. § 156. The agent of said assignee requests that all correspondence and telephone communications be directed to the following person at the mailing address and telephone number hereafter given:

Tracey B. Davies  
VINSON & ELKINS L.L.P.  
2300 First City Tower  
1001 Fannin Street  
Houston, Texas 77002-6760  
(512) 495-8619

The undersigned hereby declares that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the patent.

ASSIGNEE:

IMMUNEX CORPORATION

By: Michael Kirschner

Name: Michael Kirschner

Title: Vice President, <sup>HKK</sup> of Intellectual Property

Date: August 25, 2000

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for Patent Term Extension: )  
Immunex Corporation )  
Reissue Patent No.: 36,755 )  
Filed: December 22, 1998 ) Atty Dkt: IMM200/4-001EX  
For: DNA ENCODING TUMOR )  
NECROSIS FACTOR – ALPHA )  
AND BETA RECEPTORS )

**REQUEST FOR ADDITIONAL CERTIFIED COPIES  
OF PATENT TERM EXTENSION CERTIFICATE**


Ms. Karin Tyson  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner for  
Patent Examination Policy  
2021 South Clark Place  
Arlington, VA 22202

Dear Ms. Tyson:

Applicant requests ten (10) additional certified copies of the Patent Term Extension Certificate when it is granted. You are hereby authorized to deduct the fee for these certified copies from our Debit Account No. 22-0365/IMM200/4-001EX. Please notify my office when these certified copies are ready, so that I can arrange to have them retrieved directly from your office.

Please acknowledge receipt of this document via facsimile number (512) 236-3215. Should you have any questions regarding this matter, please contact the undersigned at (512) 495-8619.

Respectfully submitted,

  
Tracey B. Davies  
Reg. No. 44,644

Vinson & Elkins L.L.P.  
2300 First City Tower  
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Date: April 9, 2002